

02/03/2005 13:28 FAX 6123329081

MERCHANT & GOULD

021

**RECEIVED
CENTRAL FAX CENTER**

FEB 03 2005

**EXHIBIT A
ATTACHED TO RESPONSE TO
REQUIREMENT FOR INFORMATION
DATED FEBRUARY 3, 2005
SERIAL NO. 09/614.631**

PAGE 6/21 * RCVD AT 2/3/2005 2:28:17 PM [Eastern Standard Time] * SVR:USPTO-EFAX-1/1 * DNIS:8729306 * CSID:6123329081 * DURATION (mm-ss):07-56

BEST AVAILABLE COPY

Substance	Limitations
Petroleum hydrocarbon resins (cyclopentadiene-type)	For use only as an adjunct at levels not to exceed 30 percent weight in blends with: (1) Polypropylene complying with paragraph (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), (x), (y), (z), (aa), (ab), (ac), (ad), (ae), (af), (ag), (ah), (ai), (aj), (ak), (al), (am), (an), (ao), (ap), (aq), (ar), (as), (at), (au), (av), (aw), (ax), (ay), (az), (ba), (bb), (bc), (bd), (be), (bf), (bg), (bh), (bi), (bj), (bk), (bl), (bm), (bn), (bo), (bp), (bq), (br), (bs), (bt), (bu), (bv), (bw), (bx), (by), (bz), (ca), (cb), (cc), (cd), (ce), (cf), (cg), (ch), (ci), (cj), (ck), (cl), (cm), (cn), (co), (cp), (cq), (cr), (cs), (ct), (cu), (cv), (cw), (cx), (cy), (cz), (da), (db), (dc), (dd), (de), (df), (dg), (dh), (di), (dj), (dk), (dl), (dm), (dn), (do), (dp), (dq), (dr), (ds), (dt), (du), (dv), (dw), (dx), (dy), (dz), (ea), (eb), (ec), (ed), (ee), (ef), (eg), (eh), (ei), (ej), (ek), (el), (em), (en), (eo), (ep), (eq), (er), (es), (et), (eu), (ev), (ew), (ex), (ey), (ez), (fa), (fb), (fc), (fd), (fe), (ff), (fg), (fh), (fi), (fj), (fk), (fl), (fm), (fn), (fo), (fp), (fq), (fr), (fs), (ft), (fu), (fv), (fw), (fx), (fy), (fz), (ga), (gb), (gc), (gd), (ge), (gf), (gg), (gh), (gi), (gj), (gk), (gl), (gm), (gn), (go), (gp), (gq), (gr), (gs), (gt), (gu), (gv), (gw), (gx), (gy), (gz), (ha), (hb), (hc), (hd), (he), (hf), (hg), (hh), (hi), (hj), (hk), (hl), (hm), (hn), (ho), (hp), (hq), (hr), (hs), (ht), (hu), (hv), (hw), (hx), (hy), (hz), (ia), (ib), (ic), (id), (ie), (if), (ig), (ih), (ii), (ij), (ik), (il), (im), (in), (io), (ip), (iq), (ir), (is), (it), (iu), (iv), (iw), (ix), (iy), (iz), (ja), (jb), (jc), (jd), (je), (jf), (jg), (jh), (ji), (jj), (jk), (jl), (jm), (jn), (jo), (jp), (jq), (jr), (js), (jt), (ju), (jv), (jw), (jx), (jy), (jz), (ka), (kb), (kc), (kd), (ke), (kf), (kg), (kh), (ki), (kj), (kk), (kl), (km), (kn), (ko), (kp), (kq), (kr), (ks), (kt), (ku), (kv), (kw), (kx), (ky), (kz), (la), (lb), (lc), (ld), (le), (lf), (lg), (lh), (li), (lj), (lk), (ll), (lm), (ln), (lo), (lp), (lq), (lr), (ls), (lt), (lu), (lv), (lw), (lx), (ly), (lz), (ma), (mb), (mc), (md), (me), (mf), (mg), (mh), (mi), (mj), (mk), (ml), (mm), (mn), (mo), (mp), (mq), (mr), (ms), (mt), (mu), (mv), (mw), (mx), (my), (mz), (na), (nb), (nc), (nd), (ne), (nf), (ng), (nh), (ni), (nj), (nk), (nl), (nm), (nn), (no), (np), (nq), (nr), (ns), (nt), (nu), (nv), (nw), (nx), (ny), (nz), (oa), (ob), (oc), (od), (oe), (of), (og), (oh), (oi), (oj), (ok), (ol), (om), (on), (oo), (op), (oq), (or), (os), (ot), (ou), (ov), (ow), (ox), (oy), (oz), (pa), (pb), (pc), (pd), (pe), (pf), (pg), (ph), (pi), (pj), (pk), (pl), (pm), (pn), (po), (pp), (pq), (pr), (ps), (pt), (pu), (pv), (pw), (px), (py), (pz), (qa), (qb), (qc), (qd), (qe), (qf), (qg), (qh), (qi), (qj), (qk), (ql), (qm), (qn), (qo), (qp), (qq), (qr), (qs), (qt), (qu), (qv), (qw), (qx), (qy), (qz), (ra), (rb), (rc), (rd), (re), (rf), (rg), (rh), (ri), (rj), (rk), (rl), (rm), (rn), (ro), (rp), (rq), (rr), (rs), (rt), (ru), (rv), (rw), (rx), (ry), (rz), (sa), (sb), (sc), (sd), (se), (sf), (sg), (sh), (si), (sj), (sk), (sl), (sm), (sn), (so), (sp), (sq), (sr), (ss), (st), (su), (sv), (sw), (sx), (sy), (sz), (ta), (tb), (tc), (td), (te), (tf), (tg), (th), (ti), (tj), (tk), (tl), (tm), (tn), (to), (tp), (tq), (tr), (ts), (tt), (tu), (tv), (tw), (tx), (ty), (tz), (ua), (ub), (uc), (ud), (ue), (uf), (ug), (uh), (ui), (uj), (uk), (ul), (um), (un), (uo), (up), (uq), (ur), (us), (ut), (uu), (uv), (uw), (ux), (uy), (uz), (va), (vb), (vc), (vd), (ve), (vf), (vg), (vh), (vi), (vj), (vk), (vl), (vm), (vn), (vo), (vp), (vq), (vr), (vs), (vt), (vu), (vv), (vw), (vx), (vy), (vz), (wa), (wb), (wc), (wd), (we), (wf), (wg), (wh), (wi), (wj), (wk), (wl), (wm), (wn), (wo), (wp), (wq), (wr), (ws), (wt), (wu), (wv), (ww), (wx), (wy), (wz), (xa), (xb), (xc), (xd), (xe), (xf), (xg), (xh), (xi), (xj), (xk), (xl), (xm), (xn), (xo), (xp), (xq), (xr), (xs), (xt), (xu), (xv), (xw), (xx), (xy), (xz), (ya), (yb), (yc), (yd), (ye), (yf), (yg), (yh), (yi), (yj), (yk), (yl), (ym), (yn), (yo), (yp), (yq), (yr), (ys), (yt), (yu), (yv), (yw), (yx), (yy), (yz), (za), (zb), (zc), (zd), (ze), (zf), (zg), (zh), (zi), (zj), (zk), (zl), (zm), (zn), (zo), (zp), (zq), (zr), (zs), (zt), (zu), (zv), (zw), (zx), (zy), (zz).

Dated: May 29, 1996.
William K. Hubbard,
Associate Commissioner for Policy
Coordination.
[FR Doc. 96-13983 Filed 6-3-96; 8:45 am]
BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 93F-0136]

**Indirect Food Additives: Adjuvants,
Production Aids, and Sanitizers**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid as a sanitizing solution for use on food processing equipment and utensils, including food-contact surfaces in public eating places. This action responds to a petition filed by Ecolab, Inc.

DATES: Effective June 4, 1996; written objections and requests for a hearing by July 5, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration,

200 C St. SW., Washington, DC 20204, 202-418-3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 17, 1993 (58 FR 28882), FDA announced that a food additive petition (FAP 9B4371) had been filed by Ecolab, Inc., 840 Sibley Memorial Hwy., St. Paul, MN 55118. The petition proposed to amend the food additive regulations in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of an aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylene diphosphonic acid as a sanitizing solution for use on food processing equipment and utensils, including food-contact surfaces in public eating places.

While the agency used the term hydroxyethylene diphosphonic acid in the notice of filing, the agency has determined that a more specific and therefore more appropriate name for the substance is 1-hydroxyethylidene-1,1-diphosphonic acid. This more specific name will be used in the remainder of this document and in the regulation.

I. Safety and Functional Effect of Petitioned Use of the Additive

Sanitizing solutions are mixtures of chemicals that function together to sanitize food-contact surfaces and are regulated as such. Each listed component in a sanitizing solution has a functional effect; however, the agency evaluates data on the antimicrobial efficacy of the entire sanitizing solution. In addition, FDA regulations require that food-contact surface sanitizing solutions be labeled in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (§ 178.1010(d)). The subject sanitizing solution is an aqueous solution of hydrogen peroxide, acetic

acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid. The functions of these components and the basis for FDA's determination of the safety of these components in the subject sanitizing solution are described below.

A. Hydrogen Peroxide

Hydrogen peroxide functions as an antimicrobial agent in the subject sanitizing solution. Hydrogen peroxide is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(30) and (b)(38), and it is affirmed as generally recognized as safe (GRAS) for use in food with specific limitations under 21 CFR 184.1388. On the basis of the data submitted in support of the already-regulated uses of hydrogen peroxide and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of hydrogen peroxide in the subject sanitizing solution is safe (Refs. 1 and 2).

B. Acetic Acid

Acetic acid functions as an acidifier in the subject sanitizing solution. Acetic acid is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(30) and (b)(38), and it is affirmed as GRAS for use in food under 21 CFR 184.1005. On the basis of the data submitted in support of the already-regulated uses of acetic acid and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of acetic acid in the subject sanitizing solution is safe (Refs. 1 and 2).

C. Peroxyacetic Acid

Peroxyacetic acid (POA) functions as an antimicrobial agent in the subject sanitizing solution. POA is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(30) and (b)(38). On the basis of the data submitted in support of the already-regulated uses of POA and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of POA in the subject sanitizing solution is safe (Refs. 1 and 2).

D. Octanoic Acid

Octanoic acid functions as a synergist in the subject sanitizing solution. Octanoic acid is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(27), (b)(35), (b)(36), and (b)(39), and it is approved for direct use in food under 21 CFR 172.860 (caprylic acid). On the basis of the data submitted in support of the already-regulated uses of octanoic acid and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of octanoic acid in the subject sanitizing solution is safe (Refs. 1 and 2).

E. Peroxyoctanoic Acid

Peroxyoctanoic acid (POOA) is a by-product of hydrogen peroxide and octanoic acid. Because of the highly reactive nature of POOA, the actual dietary concentration of POOA is likely to be close to zero. Based on the likely dietary concentration and information submitted in the petition, FDA finds that the use of POOA in the subject sanitizing solution is safe (Refs. 1 and 2).

F. Sodium 1-Octanesulfonate

Sodium 1-octanesulfonate (SOS) functions as a surfactant in the subject sanitizing solution. SOS is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(27) and (b)(42). On the basis of the data submitted in support of the already-regulated uses of SOS and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of SOS in the subject sanitizing solution is safe (Refs. 1 and 2).

G. 1-Hydroxyethylidene-1,1-Diphosphonic Acid

1-Hydroxyethylidene-1,1-diphosphonic acid functions as a stabilizer in the subject sanitizing solution. 1-Hydroxyethylidene-1,1-diphosphonic acid is permitted as an ingredient in sanitizing solutions under § 178.1010(b)(30). On the basis of the

data submitted in support of this regulated use of 1-hydroxyethylidene-1,1-diphosphonic acid and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of 1-hydroxyethylidene-1,1-diphosphonic acid in the subject sanitizing solution is safe (Refs. 1 and 2).

H. Conclusion on Safety

As discussed above, FDA has evaluated data on the antimicrobial efficacy of the entire sanitizing solution and data in the petition and other relevant materials on the safety of each of the components of the sanitizing solution. On the basis of this evaluation, the agency concludes that these data and materials establish the safety and efficacy of the additive for use as a sanitizing solution on food-processing equipment and utensils, including food-contact surfaces in public eating places, and that the regulations should be amended in § 178.1010 as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum entitled "Safety Review of Hydrogen Peroxide, Acetic Acid, Peroxyacetic Acid, Octanoic Acid, Peroxyoctanoic Acid, Sodium 1-Octanesulfonate, and Hydroxyethylidene

Diphosphonic Acid as Sanitizer Components," dated June 12, 1995.
2. Memorandum entitled "FAF3071 (MATS #704 M2.1): KK-6094 - Sanitizer Formulation Consisting of Hydrogen Peroxide, Octanoic Acid, Peroxyacetic Acid, Sodium 1-Octanesulfonate, and 1-Hydroxyethylidene-1,1-Diphosphonic Acid." Klenzade submission of 3/9/93, dated October 20, 1993.

IV. Filing of Objections

Any person who will be adversely affected by this regulation may, any time on or before July 5, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.1010 is amended by adding new paragraphs (b)(45) and (c)(39) to read as follows:

Federal Register / Vol. 61, No. 108 / Tuesday, June 4, 1996 / Rules and Regulations 28053

§ 178.1010 Sanitizing solutions.

(b) (45) An aqueous solution of hydrogen peroxide, acetic acid, peroxyacetic acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate, and 1-hydroxyethylidene-1,1-diphosphonic acid. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places, subject to the limitations in paragraph (c)(39) of this section.

(c) (39)(i) The solution identified in paragraph (b)(45) of this section, when used on food processing equipment and utensils, including dairy and beverage-processing equipment but excluding food-contact surfaces in public eating places and dairy and beverage containers, shall provide when ready for use at least 72 parts per million and not more than 216 parts per million of hydrogen peroxide; at least 46 parts per million and not more than 138 parts per million of peroxyacetic acid; at least 40 parts per million and not more than 122 parts per million of octanoic acid (including peroxyoctanoic acid); at least 281 parts per million and not more than 686 parts per million of acetic acid; at least 7 parts per million and not more than 34 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 36 parts per million and not more than 109 parts per million of sodium 1-octanesulfonate.

(ii) The solution identified in paragraph (b)(45) of this section, when used on food-contact equipment and utensils in warewashing machines in public eating places, at temperatures no less than 120 °F (49 °C) shall provide when ready for use at least 30 parts per million and not more than 91 parts per million of hydrogen peroxide; at least 19 parts per million and not more than 58 parts per million of peroxyacetic acid; at least 17 parts per million and not more than 52 parts per million of octanoic acid (including peroxyoctanoic acid); at least 119 parts per million and not more than 290 parts per million of acetic acid; at least 3 parts per million and not more than 14 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 15 parts per million and not more than 46 parts per million of sodium 1-octanesulfonate.

(iii) The solution identified in paragraph (b)(45) of this section, when used on dairy or beverage containers, shall provide when ready for use at least 36 parts per million and not more than

108 parts per million of hydrogen peroxide; at least 23 parts per million and not more than 69 parts per million of peroxyacetic acid; at least 20 parts per million and not more than 61 parts per million of octanoic acid (including peroxyoctanoic acid); at least 140 parts per million and not more than 343 parts per million of acetic acid; at least 3 parts per million and not more than 17 parts per million of 1-hydroxyethylidene-1,1-diphosphonic acid; and at least 18 parts per million and not more than 55 parts per million of sodium 1-octanesulfonate.

Dated: May 24, 1996.

Fred R. Shank.

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-13982 Filed 6-3-96; 8:45 am]

BILLING CODE 4180-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 40 and 48

[TD 8659]

RIN 1545-AR92

Gasoline and Diesel Fuel Excise Tax; Registration Requirements; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations [TD 8659] which were published in the Federal Register for Thursday, March 14, 1996 (61 FR 10450). The final regulations relate to the taxes on gasoline and diesel fuel reflecting and implementing certain changes made by the Omnibus Budget Reconciliation Act of 1993.

EFFECTIVE DATE: March 14, 1996.

FOR FURTHER INFORMATION CONTACT: Frank Boland (202) 622-3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to these corrections are under sections 4081 and 4101 of the Internal Revenue Code.

Need for Correction

As published, [TD 8659] contains errors that are in need of clarification.

Correction of Publication

Accordingly, the publication of final regulations which are the subject of FR Doc. 96-5586 is corrected as follows:

§ 48.4101-1 [Corrected]

On page 10460, column 2, paragraph (i)(3)(ii)(D), lines 4 and 5 are corrected by merging the two lines to read "paragraph (i) of this section, without regard to".

Cynthia E. Grigsby,
Chief, Regulations Unit, Assistant Chief Counsel (Corporate).
[FR Doc. 96-13721 Filed 6-3-96; 8:45 am]
BILLING CODE 4830-01-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

[Docket No. T-015A]

North Carolina State Plan: Approval of Revised Compliance Staffing Benchmarks

AGENCY: Department of Labor, Occupational Safety and Health Administration (OSHA).

ACTION: Approval of revised State compliance staffing benchmarks.

SUMMARY: This document amends Subpart I of 29 CFR 1952 to reflect the Assistant Secretary's decision to approve revised compliance staffing benchmarks of 64 safety inspectors and 50 industrial hygienists for the North Carolina State plan.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Anne Cyr, Acting Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3637, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 219-8148.

SUPPLEMENTARY INFORMATION:

Background

Section 18 of the Occupational Safety and Health Act of 1970 ("the Act," 29 U.S.C. 851 et seq.) provides that States which desire to assume responsibility for developing and enforcing occupational safety and health standards may do so by submitting, and obtaining Federal approval of, a State plan. Section 18(c) of the Act sets forth the statutory criteria for plan approval, and among these criteria is the requirement that the State's plan provide satisfactory assurances that the